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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,365

08/14/2003

Michael S. H. Chu

MIY-P03-024

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7590

09/12/2006

Patent Group
Ropes & Gray LLP
One International Place
Boston, MA 02110

EXAMINER

POUS, NATALIE R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,365

Applicant(s)

CHU ET AL.

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-36 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-28 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) .
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/22/04, 3/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments/Remarks

Regarding the combination of Giesy and Skiba

Applicant's arguments filed 7/7/06 have been fully considered but they are not persuasive. Applicant argues that the combination of Giesy and Skiba do not meet the limitations of the claims because the second leg of Skiba does not extend in the distal direction. Examiner respectfully disagrees. Examiner points out the claim 9 states "the second leg extending axially in a distal direction along the shaft." Examiner asserts that leg 2 as described in the previous office action extends in the distal direction, as there is no limitation in the claim as to what constitutes the "beginning" or "end" of the leg. As such, the second leg may be interpreted as extending either proximally or distally. Thus, examiner sustains the previous rejections of claims 10-17, 19-20, 24-25, 28-34 and 35-36 with respect to the combination of Giesy and Skiba.

Regarding amended claim 27, applicant argues that the combination of Giesy and Skiba and further as a matter of design choice does not teach the structure and function of amended claim 27, in particular the function of forcing a loop past a narrowing to lock the loop inside a slot. Examiner respectfully disagrees. As indicated in the previous office action, examiner concedes that the combination of Giesy and Skiba does not explicitly teach a configuration wherein the slotted connector includes a narrowing, and wherein the narrowing includes a protuberance in a wall. However, Skiba does teach wherein the device may comprise a number of different configurations, including combinations of the embodiments of figs. 11-17, and not

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limited to those depicted in figures 11-17 (Column 7, proximate lines 42-55). Further, the configuration of Fig. 12 includes protuberance 1206 for the purpose of which may trap a suture from either portion, thus performing the stated function of locking the suture past the protuberance to serve as a barrier for the filaments exit. Thus examiner sustains that the rejection as a matter of design choice is proper and is therefore sustained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

are

Claims 9-13, 18-21 and 26, ^{are}rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy et al. (US 5152749) in view of Skiba et al. (US 6723107). Giesy teaches an implant placement device comprising the following:

- a connector pair (44, 46) for attaching a medical implant (40) to a delivery device

(10)

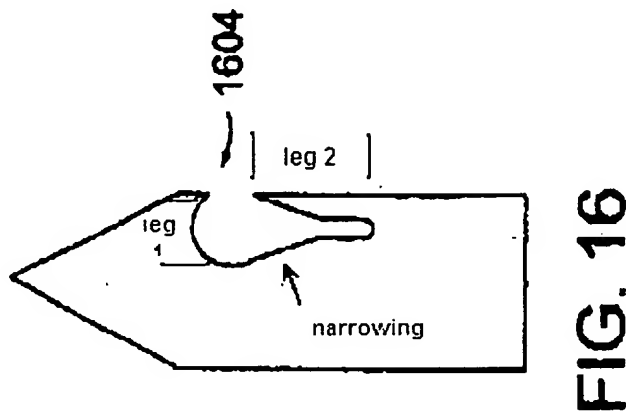
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- the connector pair comprising, a closed loop connector (44) located at an end of a medical implant (40)
- a slotted connector (46) formed in a distal end (20b) of a shaft (20) of a delivery device (10)
- for interfitting with the closed loop connector of the medical implant (fig. 3)
- wherein the closed loop connector is capable of being substantially triangular in shape. It is noted that the closed loop connector is formed of a filamentous material, which is inherently malleable into any shape including triangular.
- a freely slidable tubular sleeve (22) on the shaft for sliding over and covering the slotted connector subsequent to interfitting the closed loop connector with the slotted connector (fig. 4).
- the closed loop material is formed from a semi-flexible, shape retaining material (Column 6, proximate lines 50-60).
- the closed loop connector is formed from a suturing material (Column 6, proximate lines 50-60).
- wherein the freely slidable tubular sleeve (22) is sized relative to the shaft so that it is capable of sliding over the slotted connector in response to the shaft being withdrawing from a body of a patient.

Geisy fails to disclose wherein the slotted connector includes first and second legs, the first leg extending radially into the shaft and the second leg extending axially in

a distal direction along the shaft and includes a narrowing for locking the looped connector into the second leg.

Skiba teaches a suturing apparatus for capturing looped portions (fig. 16) see below:



wherein the distal portion comprises a first leg and a second leg, and the second leg includes narrowing in order to further secure the loop material in the slotted connector. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Geisy with a first and second leg, and wherein the second leg comprises a narrowing in order to further secure the loop material in the slotted connector.

The combination of Giesy and Skiba further teaches the following limitations

- wherein the second leg is longer than the first leg (fig. 16)
- the second leg extends distally at a 90 degree angle to the first leg
- the narrowing is formed where the second leg initially extends from the first leg

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- the width of the narrowing is less than that of the loop material (Skiba Column 4 proximate lines 27-35)

Claims 14-17, 24-25, 27, 28 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Giesy and Skiba as applied to claims 9 and 21 above, and further as a matter of design choice.

Regarding the limitations requiring protuberances located in different portions of the slotted connector and wherein the second leg is spherical in shape, Skiba teaches wherein the slotted portion may comprise a number of different configurations (figs 11-17) all with the same goal of securing the loop material in the slotted portion with a narrowing as in fig 16, or a protuberance as in fig 12 wherein the portion at (1206) makes the slot narrower than the loop material (column 3, proximate lines 60-65). Since it appears that the slot structures of Skiba perform the function of securing the loop material equally well as that disclosed in the application, it would have been an obvious matter of design choice to modify the combination of Giesy and Skiba with protuberances located in different portions of the slotted portion.

Regarding the limitation wherein the freely slidable tubular sleeve extends past the base portion of the closed loop connector onto the end of the medical implant, Giesy teaches wherein the sleeve extends over the slotted portion in the distal end of the shaft (fig. 4). Since it appears that the device of Giesy performs the task of holding the closed loop portion to the end of the shaft equally well and the applicant has not disclosed that extending the sheath past the end of the shaft and onto the end of the

medical implant is for any particular purpose or provides any advantage over the embodiment wherein the sleeve extends just over the loop portion, it would have been an obvious matter of design choice to provide the sleeve past the loop portion and onto the implant.

Regarding the limitation wherein the freely slidable tubular sleeve includes an aperture for aligning with the first leg of the slotted connector during interfitting of with the closed loop connector, Giesy teaches wherein the sleeve is closed, and extends over the slotted portion in the distal end of the shaft (fig. 4). Since it appears that the device of Giesy performs the task of holding the closed loop portion to the end of the shaft equally well and the applicant has not disclosed that providing an aperture in the sleeve is for any particular purpose or provides any advantage over the embodiment wherein the sleeve is solid, it would have been an obvious matter of design choice to provide the sleeve with an aperture in alignment with the slotted portion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
8/30/06


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/4/06